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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,320	03/01/2002	Andrew H. Cragg	BSI-030US7	3784

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EXAMINER
BUI, VY Q

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,320	CRAGG, ANDREW H.	
	Examiner	Art Unit	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amendment entered 5/14/2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16 and 18-28* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-12 and 18-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1/11, 7-8, 9, 12 respectively of U.S. Patent No. 5,683,448 and claims 1-3, 7-8, 21-22, 24-31 respectively of U.S. Patent No. 6,174,328. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same subject matters as following: a stent member of a shape memory material such as nitinol, the stent member including hoops with elongate members forming vertices, wherein some of the vertices axially abut and are individually connected to opposite pointed vertices, a graft member outwardly or inwardly attached to the stent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10-11, 13-15, 16, 18, 21 + 12 + 19-20 + 22-23, 25-26, 28 + 24, 27

1. Claim ~~12~~ and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARONE et al (5,360,443) in view of GIANTURCO et al. (5,035,706).

As to claims 10-11, and 13-15, BARONE (Fig. 2-4; column 6, lines 32-45) discloses a stent-graft combination including graft member 160, stent member 166/172 of stainless steel having diamond shaped openings to define elongate elements, with pairs of the elongate elements forming vertices. The vertices axially abut and are individually connected to the opposite pointed vertices. Notice that stainless steel is a resilient and shape memory material. BARONE Fig. 3 also shows graft 160 covers stent 166/172. BARONE does not disclose a stent structure having separate and distinct hoops as recited in the claims. However, to provide a combined stent that permits the combination of several interlocked separate and distinct hoops for insertion into a body passageway without multiple catheterization, GIANTURCO (lines 20-24, col. 2) discloses a stent having separate and distinct hoops and vertices connected together in a manner as recited in the claims and as shown in the Fig. 6 below:

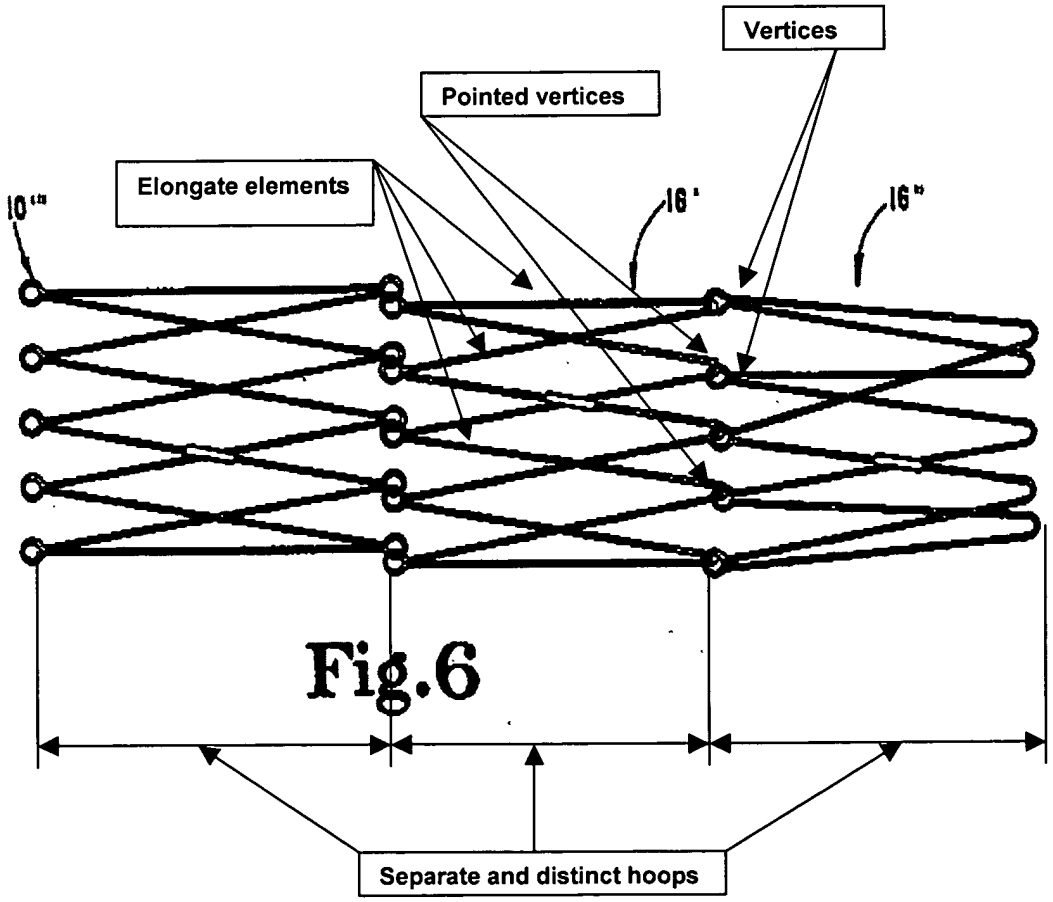

Fig.6

In view of GIANTURCO, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct a stent-graft combination as claimed by replacing BARONE stent structure with GIANTUREO stent structure of stainless steel so as to provide a longer combined stent of connected shorter stents/hoops, which does not require multiple catheterization (or to avoid a multiple catheterization if the shorter hoops/stents are not connected) for deployment into a blood vessel (GIANTURCO: lines 20-24, col. 2).

As to claims 16 and 18, BARONE (Fig. 2-4, column 6, lines 12-16) discloses graft 160 disposed on the outer surface of stent 172 and attached to stent 166/172 by suture 170.

As to claim 21, BARONE (column 6, lines 55-66) discloses graft 160 of polyester (Dacron) or poly-tetrafluoroethylene material (Teflon).

2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over BARONE et al (5,360,443) in view of GIANTURCO et al. (5,035,706) and further in view of DOTTER (4,503,569).

BARONE and GIANTURCO disclose substantially all structural limitations as recited in the claim, except for the stent of a shape memory nitinol alloy. Nitinol stent is well-known in the art at the time the invention was made. DOTTER (Figs. 1-6) discloses stent 10 of Nitinol, which can be expanded from a deployment/unexpanded profile to a working/expanded profile by a change in temperature (abstract, lines 1-11). In view of DOTTER, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make BARONE stent 166/172 of a nitinol material so that the stent can be transformed from a deployment /unexpanded profile to a working/expanded profile by temperature change.

3. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARONE et al (5,360,443) in view of GIANTURCO et al. (5,035,706).

As to claim 19, BARONE and GIANTURCO disclose substantially all structural limitations as recited in the claim, except for the graft to be secured to the inside surface

of stent 166/172. It is well known to secure a graft member to a stent member so as the graft covering the inside surface of the stent to provide a smooth surface for a fluid/blood flow. It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach graft 160 to the inside surface of stent 166/172 to provide a smooth surface to promote a blood flow in a blood vessel.

As to claim 20, BARONE and GIANTURCO disclose the claimed invention except for a drug disposed on graft 160. It is well known in the art to include drug (to prevent blood clotting, for example) to a graft for a treatment at a local site of a blood vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a drug to graft 160 so as to provide a treatment to a local site of a blood vessel.

4. Claims 22-23, 25-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARONE et al (5,360,443) in view of GIANTURCO et al. (5,035,706) and further in view of GIANTURCO (4,580,568).

As to claims 22-23, 25-26 and 28, in addition to the above 103(a) rejection based on BARONE and GIANTURCO (5,035,706) teaching, which discloses substantially all structural limitations as recited in the claims, except for a method of reinforcing a body vessel using a tubular sheath to deploy a self-expanding elastic stent-graft as recited in the claims. However, GIANTURCO-'568 (abstract; column 3, lines 5-17; claim 8; Figs. 1-10) discloses a method for reinforcing a body vessel using a *self-expanding elastic stent 9* of stainless steel (stainless steel is an elastic and shape memory material) and *tubular sheath 15*. The GIANTURCO-'568 method includes essentially similar steps as claimed in the present invention. Since, the stent-graft in the present invention including *a self-expanding stent member*, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the stent member in BARONE stent-graft device with a self-expanding stent as taught by GIANTURCO-'706 and apply the method as taught by GIANTURCO-'568 to deploy the stent-graft device for reinforcing a body vessel as claimed.

5. Claims 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over BARONE et al (5,360,443) and GIANTURCO et al. (5,035,706) in view of GIANTURCO (4,580,568) and further in view of DOTTER (4,503,569).

As to claims 24 and 27, BARONE and GIANTURCO do not teach a self-expanding stent member of Nitinol. However, DOTTER (Figs. 1-6; column 3, lines 49-66) discloses stent 10 of a shape memory alloy nitinol, which can be cooled to a low temperature to a martensite phase (inelastic phase) so as to be compressed to a smaller deployment/unexpanded profile and when stent 10 is heated to a transition temperature, stent 10 will expand to a larger expanded profile in an austenite phase (elastic phase) to support a blood vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the stent member in BARONE stent-graft device with a self-expanding stent as taught by DOTTER and apply the method as taught by GIANTURCO to deploy the stent-graft device for reinforcing a body vessel as claimed.

Allowable Subject Matter

Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claim 10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

VQB
August 7, 2003.